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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/062,308 | 02/01/2002 | David L. Rimm | YUA-001.01 | 2553 |
| 25181 | 7590 | 10/19/2005 | EXAMINER | |
| FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110 | | | LIN, JERRY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,308

Applicant(s)

RIMM ET AL.

Examiner

Jerry Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 33-38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-32, 41 and 43 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-13, 39, 40 and 42 is/are rejected.
- 7) ☒ Claim(s) 8 and 14-29 is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Applicants' arguments, filed July 5, 2005 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-13, 39, 40, and 42 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by Harris et al. (US 2003/0036855).

Regarding claims 1 and 10, Harris et al. teach a method that includes identifying portions of a first image that corresponds to a first defined area (e.g. nuclei) (page 22, paragraph 0341-page 23, paragraph 0346); identifying portions of a second image of a cell that corresponds to at least one biomarker (e.g. Cy3 or G-protein receptor) (page 22, paragraph 0341-page 23, paragraph 0346); superimposing portions of the second image against portions of the first image to identify whether the biomarker (a protein) is

localized within the defined area (page 22, paragraph 0341-page 23, paragraph 0346; Fig. 24A-26D).

Regarding claims 2 - 7, Harris et al. teach using images that are pixels (page 22, paragraph 0341-page 23, paragraph 0346); determining the intensity of the pixels corresponding to the first defined area of the cell or a biomarker (page 16, paragraph 0024- page 17, paragraph 0244; page 22, paragraph 0341-page 23, paragraph 0346; Fig. 24A-26D); comprising reducing representation of out of focus elements in the image (assigning unqualified pixels a value of 0) (page 16, paragraph 0024- page 17, paragraph 0244).

Regarding claims 9 and 12, Harris et al. teach a method wherein the defined area is a nucleus or other organelles (page 22, paragraph 0341-page 23, paragraph 0346; page 21, paragraph 0321).

Regarding claims 11, 13, 39, 40, and 42, Harris et al. teach a method that includes using a stain for the first sub-cellular compartment in the first image and a second stain for at least one biomarker (page 22, paragraph 0341-page 23, paragraph 0346); determining the intensity value for the first stain and the second stain and superimposing the images to indicate that the biomarker is within the first sub-cellular compartment (page 16, paragraph 0024- page 17, paragraph 0244; page 22, paragraph 0341-page 23, paragraph 0346; Fig. 24A-26D); a stain is a fluorophore (pages 14-15, paragraph 0188); fixing the cells (page 4, paragraph 0034); using cells that are in tissue (page 5, paragraph 0069; page 14, paragraph 0182).

Allowable Subject Matter

Claims 8 and 14-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 30-32, 41 and 43 are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 6:30-5:00, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

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contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

Ardin H. Marschel 10/16/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

JL